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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/508,487      | 03/10/2000  | SVEN BERGSTROM       | 454312-3150         | 9076             |

20999 7590 09/25/2003

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| EXAMINER |
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SWARTZ, RODNEY P

| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/508,487      | BERGSTROM, SVEN |
| Examiner                     | Art Unit        |                 |
| Rodney P. Swartz, Ph.D.      | 1645            |                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 5September2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 73-106 and 108-111 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 73-106,108-111 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of an Information Disclosure Statement, filed on 5September2003, has been entered.

It is noted that the request also requests consideration of Applicants' response received 16December2002, paper#16. This response had already been entered and considered in the Office Action, mailed 11March2003, paper#17, which follows immediately.

2. Applicants' Response to Office Action, received 16December2002, paper#16 is acknowledged.

The following is a quotation of 37 CFR §1.4(c ) which forms the basis for all correspondence:

" Since different matters may be considered by different branches or sections of the Patent and Trademark Office, each distinct subject, inquiry, or order should be contained in a separate letter to avoid confusion and delay in answering letters dealing with different subjects."

Applicants' correspondence contains three different requests: 1) Response, 2) Conditional Request for Interview with Supervisory review, and 3) Extension of time.

If, upon receipt of this Office Action, applicants still desire an interview, one may be scheduled as set forth in 37 CFR §1.133 by calling the examiner of record at (703)308-4244.

Claims 73,74,75, 76, 77, 78, 82, 83, and 84 have been amended. Claim 107 has been canceled without prejudice.

3. Claims 73-106 and 108-111 are pending and under consideration.

**Rejections Withdrawn**

4. The rejection of claims 73-106 and 108-111 under 35 U.S.C. 112, second paragraph, as being indefinite for "substantial" reactivity and "derived", is withdrawn in light of the claim amendments.
5. The rejection of claims 78, 84, and 85 under 35 U.S.C. 112, first paragraph, scope of enablement for all polyclonal rabbit antibodies raised against a 13 kDa polypeptide from *B. burgdorferi* strain B313, is withdrawn in light of the amendment of the claims.

**Rejections Maintained**

6. The rejection of claims 73-77, 79-83, 86-106 and 108-111 under 35 U.S.C. 112, first paragraph, scope of enablement for all polyclonal rabbit antibodies raised against a 13 kDa polypeptide from *B. burgdorferi* strain B313, is maintained.

Applicants argue that the use of transition terms "consisting essentially of" or "consists essentially of" exclude elements found in the prior art and that the terms provide that the first and second polypeptides do not encompass polypeptides that do not have the basic or novel characteristics.

The examiner has considered applicants' argument, but does not find it persuasive. The instant claim 73 is drawn to "an isolated polypeptide" without any designation of the source of the claimed polypeptide, the function of the claimed polypeptide, or its structure, except for one embodiment wherein the claimed polypeptide is identical in amino acid sequence to another polypeptide which is a 13 kDa surface exposed polypeptide extracted from *B. burgdorferi sensu lato* and said polypeptide may or may not be lipidated. However, the amino acid sequence of this "other" polypeptide is not elucidated. Therefore, the identity of the claimed polypeptide remains unknown because of the uncertainty of the binding epitope of the polyclonal rabbit

antibody. The use of the transition term "consists essentially of" the amino acid sequence 1-167 of SEQ ID NO:19 does not correct the uncertainty of the binding epitope because the terminology applies only the function of SEQ ID NO:19, a function not identified.

Claim 74 does not correct the deficiencies of claim 73 because claim 74 states that the claimed polypeptide "consists essentially of" an amino acid sequence of a fourth polypeptide which is present in various cell preparations, but absent in others. However, the amino acid sequence of this fourth polypeptide is also absent.

Claim 75 does not correct the deficiencies of claim 73 because the only new characteristic is that the claimed polypeptide "consists essentially of" at least a portion of an unidentified amino acid sequence of a 13 kDa protein present in whole cell preparation of some *Borrelia* but not all *Borrelia*. The claim does not define what constitutes "a portion", i.e., one amino acid or perhaps 100 amino acids.

Claim 76 does not correct the deficiencies of claim 73 because the new characteristic that the polypeptide "consists essentially of" at least one epitope of any protein of a whole cell preparation of *Borrelia* does require that the epitope be the one which binds to the antibody utilized to identified the claimed polypeptide.

Claim 77 does not correct the deficiencies of claim 73 because it is identical to claim 76 except that the unknown protein of a whole cell preparation of *Borrelia* now has an apparent molecular weight of 13 kDa.

Claims 79 and 80 do not correct the deficiencies of claim 73 because said polypeptide now has an identical amino acid sequence to that of an unidentified protein from a whole cell preparation of *Borrelia* wherein said unidentified protein has a molecular weight of 13 kDa.

Claim 81 does not correct the deficiencies of claim 73 because the claim states that the claimed polypeptide is the third polypeptide. However, the third polypeptide in claim 73 is only identified by it being a 13 kDa surface polypeptide extracted from *Borrelia burgdorferi sensu lato*.

Claim 82 does not correct the deficiencies of claim 73 because the claim recites that the claimed polypeptide "has" an amino sequence exhibiting  $\geq 50\%$  identity with select sequences. The open terminology "has" does not exclude additional amino acids outside the region which exhibits the percent identity. Therefore, the binding of the antibody may occur in this unidentified region.

Claim 83 does not correct the deficiencies of claim 73 because the claimed polypeptide is encoded by a nucleotide sequence exhibiting  $\geq 70\%$  identity with select nucleotide sequences. However, the claimed binding region of the polypeptide to which the polyclonal antibody binds may be encoded by the unknown 30% of the nucleotide sequence.

Claims 86 and 87 do not correct the deficiencies of claim 73 because they merely state that they are a fusion protein wherein the first fusion partner is the claimed polypeptide of claim 73.

Claim 88 does not correct the deficiencies of claim 73 because it is drawn to a fusion polypeptide wherein the first polypeptide is the unknown polypeptide of claim 73 and the second fusion polypeptide may be any T-cell or B-cell epitope of any source.

Claims 89-106 and 108-111 do not correct the deficiencies of claim 73 because they merely state that the amount of the unknown polypeptide be sufficient to induce some immunological response, or that the unknown polypeptide be synthesized by certain methods.

Applicants argue that the various epitopes identified in claim 78 and hence identified in the application are not "unknown".

The examiner has considered applicants' argument concerning the epitopes in newly amended claims 78, 84, and 85 and finds them persuasive due to the new restricted that the polypeptide "consists essentially of" the specified sequences.

#### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 78, 84, and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 78 now recites that the claimed polypeptide of claim 73 consists essentially of at least one of the 18 nonoverlapping sequences listed. However, it is unclear how all of these nonoverlapping sequences listed can fulfill the requirement that they "bind specifically" with a polyclonal rabbit antibody raised against a second 13 kDa polypeptide from *B. burgdorferi* B313.

Amended claim 84 now recites that the claimed polypeptide of claim 83 "consists essentially of" an amino acid sequence selected from SEQ ID Nos: 19, 21, and 23. As with claim 78, it is unclear how each of these sequences can fulfill the requirement that they "bind specifically" with the same polyclonal rabbit antibody.

Claim 85 depends from amended claim 84 and therefore claims a polypeptide which now "consists essentially of" an amino acid sequence selected from SEQ ID Nos: 19, 21, and 23. As

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with claim 84, it is unclear how each of these sequences can fulfill the requirement that they "bind specifically" with the same polyclonal rabbit antibody.

### Conclusion

9. No claims are allowed.
10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

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September 23, 2003